



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10108, CMS-10243, CMS-10383, CMS-10609, CMS-R-131 and CMS-10662]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by **[INSERT DATE 30 DAYS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions:

OMB, Office of Information and Regulatory Affairs

Attention: CMS Desk Officer

Fax Number: (202) 395-5806 OR

E-mail: OIRA_submission@omb.eop.gov

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web Site address at Web Site address at
<https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>
1. E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.
2. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term “collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicaid Managed Care Regulations; *Use:* The requirements contained in this information collection request implement regulations that allow states greater flexibility to implement mandatory managed care programs, implement new beneficiary protections, and eliminate certain requirements viewed by state agencies as impediments to the growth of managed care programs. Information collected includes information about managed care programs, grievances and appeals, enrollment broker contracts, and managed care organizational capacity to provide health care services. Medicaid enrollees use the information collected and reported to make informed choices regarding health care, including how to access health care services and the grievance and appeal system. States use the

information collected and reported as part of its contracting process with managed care entities, as well as its compliance oversight role. We use the information collected and reported in an oversight role of state Medicaid managed care programs. *Form Number:* CMS-10108 (OMB control number: 0938-0920); *Frequency:* Occasionally; *Affected Public:* Individuals or households, Private sector (business or other for-profit and not-for-profit institutions), and State, local or Tribal Government; *Number of Respondents:* 628; *Total Annual Responses:* 22,564,877; *Total Annual Hours:* 1,371,968. (For policy questions regarding this collection contact Amy Gentile at 410-786-3499.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Testing Experience and Functional Tools: Functional Assessment Standardized Items (FASI) Based on the CARE Tool; *Use:* In 2012, CMS funded a project entitled, Technical Assistance to States for Testing Experience and Functional Tools (TEFT) Grants. One component of this demonstration is to amend and test the reliability of a setting-agnostic, interoperable set of data elements, called “items,” that can support standardized assessment of individuals across the continuum of care. Items that were created for use in post-acute care settings using the Continuity Assessment Record and Evaluation (CARE) tool have been adopted, modified, or supplemented for use in community-based long-term services and supports (CB-LTSS) programs. This project will test the reliability and validity of the function-related assessment items, now referred to as Functional Assessment Standardized Items (FASI), when applied in community settings, and in various populations: elders (65 years and older);

younger adults (18-64) with physical disabilities; and adults of any age with intellectual or developmental disabilities, with severe mental illness, or with traumatic brain injury.

Individual-level data will be collected two times using the TEFT FASI Item Set. The first data collection effort will collect data that can be analyzed to evaluate the reliability and validity of the FASI items when used with the five waiver populations. Assessors will conduct functional assessments in client homes using the TEFT FASI Item Set. Changes may be recommended to individual TEFT FASI items, to be made prior to releasing the TEFT FASI items for use by the states. The FASI Field Test Report will be released to the public.

The second data collection will be conducted by the states to demonstrate their use of the FASI data elements. The assessment data could be used by the states for multiple purposes. They may use the standardized items to determine individual eligibility for state programs, or to help determine levels of care within which people can receive services, or other purposes. In the second round of data collection, states will demonstrate their proposed uses, manage their FASI data collection and conduct their own analysis, to the extent they propose to do such tasks. The states have been funded under the demonstration grant to conduct the round 2 data collection and analysis. These states will submit reports to CMS describing their experience in the Round 2 data collection, including the items they collected, how they planned to use the data, and the types of challenges and successes they encountered in doing so. The reports may be used by CMS in their evaluation of the TEFT grants. *Form Number:* CMS-10243 (OMB control number: 0938-1037); *Frequency:* On occasion; *Affected Public:* Individuals and Households; *Number of*

Respondents: 5,650; Total Annual Responses: 5,650; Total Annual Hours: 2,825. (For policy questions regarding this collection contact Kerry Lida at 410-786-4826.)

3. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Review and Approval Process for Waivers for State Innovation; *Use:* The information required under this collection is necessary to ensure that states comply with statutory and regulatory requirements related to the development and implementation of section 1332 waivers. States seeking waiver authority under section 1332 of the PPACA are required to meet certain requirements for applications, public notice, and reporting. The authority for these requirements is found in section 1332 of the PPACA. This information collection reflects the requirements provided in the final rules, 77 FR 11700, published February 27, 2012. Additionally, on October 24, 2018, the Departments published guidance, 83 FR 53575, that provides supplementary information about the requirements that must be met for the approval of a section 1332 waiver, the Secretaries application review procedures, the calculation of pass-through funding, certain analytical requirements, and operational considerations. This guidance supersedes the guidance related to section 1332 of the PPACA that was previously published on December 16, 2015. This information collection also reflects the requirements outlined in a state's specific terms and conditions (STCs), as part of the approval of a state's section 1332 waiver application. *Form Number:* CMS-10383 (OMB control number 0938-NEW); *Frequency:* Occasionally; *Affected Public:* State Governments; *Number of Respondents:* 12; *Total Annual Responses:* 212; *Total Annual Hours:* 4,016. (For policy questions regarding this collection contact Michelle Koltov at 301-492-4225.)

4. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicaid Program Face-to-Face Requirements for Home Health Services and Supporting Regulations; *Use:* 42 CFR 440.70(f) and (g) requires that physicians (or for medical equipment, authorized non-physician practitioners (NPPs) including nurse practitioners, clinical nurse specialists and physician assistants) document that there was a face-to-face encounter with the Medicaid beneficiary prior to the physician making a certification that home health services are required. The burden associated with this requirement is the time and effort to complete this documentation. The burden also includes writing, typing, or dictating the face-to-face documentation and signing/dating the documentation. *Form Number:* CMS-10609 (OMB control number: 0938-1319); *Frequency:* Occasionally; *Affected Public:* Private sector (business or other for-profits); *Number of Respondents:* 381,148; *Total Annual Responses:* 1,143,443; *Total Annual Hours:* 190,955. (For policy questions regarding this collection contact Alexandra Smilow at 410-786-0790.)

5. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Advance Beneficiary Notice of Noncoverage (ABN); *Use:* The use of the written Advance Beneficiary Notice of Non-coverage (ABN) is to inform Medicare beneficiaries of their liability under specific conditions. This has been available since the “limitation on liability” provisions in section 1879 of the Social Security Act (the Act) were enacted in 1972 (P.L. 92-603). ABNs are not given every time items and services are delivered. Rather, ABNs are given only when a physician, provider, practitioner, or supplier anticipates that Medicare will not provide payment

in specific cases.

An ABN may be given, and the beneficiary may subsequently choose not to receive the item or service. An ABN may also be issued because of other applicable statutory requirements other than §1862(a)(1) such as when a beneficiary wants to obtain an item from a supplier who has not met Medicare supplier number requirements, as listed in section 1834(j)(1) of the Act or when statutory requirements for issuance specific to HHAs are applicable.

ABNs are usually given as hard copy notices during in-person patient encounters. In some cases, notification may be done by telephone with a follow-up notice mailed. Electronic issuance of ABNs is permitted as long as the beneficiary is offered the option to receive a paper copy of the notice if this is preferred. Regardless of the mode of delivery, the beneficiary must receive a copy of the signed ABN for his/her own records. Incorporation of ABNs into other automated business processes is permitted, and some limited flexibility in formatting the notice in such cases is allowed, as discussed in the form instructions. Notifiers may choose to store the required signed copy of the ABN electronically. *Form Number:* CMS-R-131 (OMB control number: 0938-0566); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 1,589,060; *Total Annual Responses:* 382,216,385; *Total Annual Hours:* 44,593,186. (For policy questions regarding this collection contact Jennifer McCormick at 410-786-2852.)

6. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Administrative Simplification HIPAA Compliance Review; *Use:* The authority for administering and enforcing compliance with the

Administrative Simplification non-privacy Health Insurance Portability and Accountability Act (HIPAA) rules has been delegated to the Centers for Medicare & Medicaid Services (CMS). (68 FR 60694 Part F, October 23, 2003) 45 CFR 160.308 states, “that the Secretary may conduct compliance reviews to determine whether covered entities are complying with the applicable administrative simplification provisions.” These reviews are conducted at the discretion of the Secretary. Title 45 CFR 160.310 requires that a covered entity provide records and compliance reports to the Secretary in cooperation with a compliance review. Title 45 CFR 160.310 provides that a covered entity must permit HHS, or its delegated entity, access during normal business hours to its facilities, books, records, and other information, and other information necessary to determine compliance, but also provides that if the Secretary determines that “exigent circumstances exist, such as when documents may be hidden or destroyed,” the covered entity must permit access at any time without notice.

The purpose of this collection is to retrieve information necessary to conduct a compliance review as described in CMS-0014-N (68 FR 60694). These forms will be submitted to the Centers for Medicare & Medicaid Services (CMS), Program Management National Standards Group, from entities covered by HIPAA Administrative Simplification regulations. This collection is not applicable to HIPAA Privacy and Security Rules. *Form Number:* CMS-10662 (OMB control number: 0938-New); *Frequency:* Occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 10; *Total Annual Responses:* 10; *Total Annual Hours:* 425. (For policy questions regarding this collection contact Cecily Austin at 410-786-0895.)

Dated: December 13, 2019.

William N. Parham, III,

Director,

Paperwork Reduction Staff,

Office of Strategic Operations and Regulatory Affairs.

4120-01-U-P

[FR Doc. 2019-27280 Filed: 12/17/2019 8:45 am; Publication Date: 12/18/2019]